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April 11, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Docket No. 00D-0053
Comments on Draft Guidance Documents:
(1) Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme;
(2) Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties

To Whom It May Concern:

Alcon Laboratories, Inc. supports the proposal that FDA actively regulate hospital and third parties that engage in the reprocessing of single-use devices (SUDs). Such regulation, and the enforcement thereof, should be commensurate with those applied to original equipment manufacturers (OEMs).

Comments on the referenced draft guidance documents follow.

I. Draft: Guidance Document: "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme"

1. Page 3: "Scope": Health care facilities that are not "acute" health care facilities should also be regulated as third party reprocessors if they reprocess SUDs.
2. Flowchart 1/Questions 2 and 3 (pages 5 and 6); and Flowchart 2/Questions 1 and 3 (pages 8 and 9): A response of "Unknown" may be appropriate in addition to "Yes" and "No." In such cases, it is recommended that a conservative approach be taken and a response of "Unknown" be handled the same as a response of "Yes."
3. Flowchart 1/Question 5 (page 6); and Flowchart 2/Questions 2a, 2b and 5 (pages 8-10): A response of "Unknown" may be appropriate in addition to "Yes" and "No." In such cases, it is recommended that a conservative approach be taken and a response of "Unknown" be handled the same as a response of "No."
4. Page 30: Appendix 2 – List of Frequently Reprocessed SUDs: Ophthalmic Section: Add "Insertion Devices and Folders". These should have a risk Category of "High" based on functional performance after resterilization.

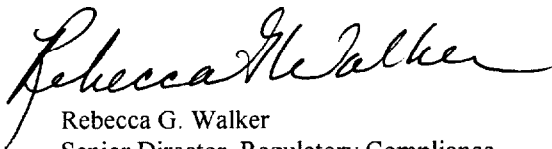
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II. Draft Guidance Document: “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals”

1. Page 4: “Scope”: Health care facilities that are not “acute” health care facilities should also be regulated as third party reprocessors if they reprocess SUDs.
2. Page 7: Item E.3. “Medical Device Reporting”: Add the following at the end of the first paragraph: “Reprocessors are responsible for reporting all adverse event MDRs associated with any SUD that has been reprocessed.”
3. Page 9: Item E.6. “Labeling”: Add the following sentence: “All reprocessed devices must be clearly labeled as “Reprocessed” and bear the name and address of the reprocessor.
4. Page 9: Item E.7. “Premarket Requirements”: There should be specific requirements for the generation of data that addresses the potential “risk of infection” and “risk of inadequate performance”. Simply demonstrating that the reprocessed SUD is comparable to a legally marketed device does not address the safety and efficacy issues inherent to a reprocessed SUD.
5. Page 9: Item E.7. “Premarket Requirements”: We do not understand how reprocessors will be able to demonstrate in their internal documentation the safety and efficacy for many moderate to high risk devices. Many of these devices are verified to their own specifications and validated to design inputs through the OEM’s design history file. This information is not only confidential but is also proprietary. Materials and specific operating specifications are often developed in conjunction with an OEM’s primary device/system . In such a case, the reprocessed SUD is an accessory working in consort with the primary system. Not knowing the operating requirements and specifications of each accessory with its own primary system, the reprocessor will be unable to properly demonstrate functionality upon reprocessing.
6. Page 14: Section F: Enforcement Priorities...: If FDA chooses to not actively enforce FDA requirements for a longer period of time than described in the guidance, the agency should publish such intentions and estimate then enforcement will be pursued.

Sincerely,



Rebecca G. Walker
Senior Director, Regulatory Compliance

RGW:ss

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